K121856

Ultraverse® 014 and 018 PTA Balloon Dilatation Catheter Line Extension

510(k) Summary

JUL 11 2012

21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc.
1625 West Third Street
Tempe, Arizona 85281
Phone: 480-379-2841
Fax: 480-449-2546
Contact: Erin Fox, Regulatory Affairs Specialist II
Date: June 25, 2012

2. Subject Device:

Device Trade Name:	Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters
Common or Usual Name:	Catheter, Angioplasty, Peripheral, Transluminal/ Catheter, Percutaneous
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

Device Trade Name:	Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters
Cleared 510(K) Number:	K093965
Date of Cleared 510(K):	03/17/10

4. Summary of Change:

The modifications from the predicate device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters, to the subject device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheter Line Extension, were to add balloon and catheter lengths.

5. Device Description:

The subject device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters Line Extension, are small vessel balloon catheters consisting of an over the wire catheter with a balloon fixed at the distal tip. The semi-compliant, low profile balloon has two radiopaque marker bands to delineate the working length of the balloon and aid in balloon placement. The coaxial, over the wire catheter is compatible with 0.014" and 0.018" guidewires, as labeled.

6. Indications for Use of Device:

The Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters, are recommended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, femoral and peroneal arteries. These catheters are not for use in coronary arteries.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheter Line Extension, are substantially equivalent to those of the predicate device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters, in terms of intended use, indications for use, materials, fundamental scientific technology, target population, operating principle, packaging, sterility assurance level and method of sterilization.

8. Performance Data:

To demonstrate the substantial equivalence of the subject device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheter Line Extension, to the predicate device, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following additional *in vitro* tests were performed:

- Dimensional Testing
- Distensibility Testing
- Fatigue Testing
- Inflation Time
- Deflation Time

- Balloon Burst Strength
- Balloon Burst Mode
- Balloon to Shaft Tensile
- Reinsertion
- Catheter Shaft Leaks
- Sheath Compatibility
- Trackability

The results from these tests demonstrate that the technological characteristics and performance criteria of the subject Ultraverse® 014 & 018 PTA Balloon Dilatation Catheter Line Extension is comparable to the predicate device and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

9. Conclusions:

The Ultraverse® 014 & 018 PTA Balloon Dilatation Catheter Line Extension met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Ultraverse® 014 & 018 PTA Balloon Dilatation Catheter Line Exentsion are substantially equivalent to the legally marketed predicate device, the Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bard Peripheral Vascular
c/o Ms. Erin Fox
1625 West 3rd St.
Tempe, AZ 85281-1740

JUL 11 2012

Re: K121856
Trade/Device Name: Ultraverse PTA catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: June 25, 2012
Received: June 26, 2012

Dear Mr. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121856

Device Name: Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters Line Extension

Indications for Use: The Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters Line Extension are recommended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popiteal, femoral and peroneal arteries. These catheters are not for use in coronary arteries.

Prescription Use__X___ AND/OR Over-The-Counter Use_____ (Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121856